Remarks

Claims 1-7, 19-32, 44-48, 73 and 74 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent Nos. 5,792,153 (Swain '153) and 5,755,730 (Swain '730) in view of U.S. Patent No. 5,954,731 (Yoon), and further in view of U.S. Patent No. 6,071,233 (Ishikawa et al. "Ishikawa"). Claim 1, as amended, describes a suturing instrument and a suture securing instrument separately insertable through a flexible tube attachable to an endoscope's shaft. Claim 1 cannot be obvious in view of the combination of Swain '153, Swain '730, Yoon, and Ishikawa if such combination fails to show each and every element of the claim. Although Swain '730 describes a device for use in cutting threads, it is not a function of the device to secure a suture and thus such device is not comparable to the claimed suture securing instrument. In fact, Swain '730 assumes that a knot (12) is already present before the device of Swain '730 is used in a patient (see Swain '730, column 2, lines 3-20). Thus, even if Yoon, Ishikawa, Swain '153, Swain '730 were combined, as the Examiner suggests, there is no description or suggestion of a suture securing device. Moreover, there is no suggestion by the combination of Yoon, Ishikawa, Swain '153, Swain '730 of any suture securing instrument having each and every limitation of Claims 22-23, or that such instrument is not part of an endoscope of Claim 24 (Swain '730 teaches the opposite at column 1, lines 25-26).

It is well established that there must be a teaching or suggestion to make the claimed combination and a reasonable expectation of success must both be found in prior art, and not based on applicant's disclosure. See In re Vaeck, 20 USPQ2d 1438, 1442 (Fed Cir. 1991). Even if the combination showed a suture securing device, there is no teaching or suggestion to make the claimed combination. In fact, the Examiner's combination actually teaches away from attachment to an endoscope outside of Yoon's shaft, as the Examiner suggests by Ishikawa, since there would already be an endoscope present by the endoscope of each device of Swain '153 or '730 (see Swain '153 at column 1, lines 50-55, and Swain '730 at column 1, lines 31-33). It is respectfully submitted that Examiner is attempting to reconstruct the present invention using hindsight knowledge gleamed from Applicants' disclosure, which it not permitted in an obviousness determination. Thus, Claim 1 along with dependent Claims 3-7, 19, 20, 22-26, 28 and 45-48 are patentable over Yoon, Swain '153, Swain '730, and Ishikawa, either alone or in combination, and withdrawal of the rejection of these Claims is requested.

Claim 2 has been rewritten in independent form with all limitations of the Claim 1 prior to this Amendment. Claim 2 describes a plurality of tube guides. Each of the claimed tube guides is attachable at a different locations along the outside of the endoscope's shaft and has an

opening through which the flexible tube extends. The claimed flexible tube is slidable through tube guide's opening in response to flexing of the endoscope's shaft. There are no tube guides at locations along the outside of the endoscope shown in FIG. 1 of Ishikawa, and no tube guides are described or even suggested by Ishikawa. At best, Ishikawa shows a single fixing clip (61) in FIGS. 6A, 6B, 9A, and 9B near the distal end of its tube (2).

The claimed tube guides provide a solution to the present invention by allowing the flexible tube to move in concert along the length of the endoscope's shaft as the endoscope moves and flexes. This offers a critical advantage to attaching an external tube to a flexible endoscope. To view and access tissues routinely targeted in modern endoscopic interventions, the endoscopist frequently rotates the endoscope and uses the device's internal steering mechanism to flex the tip of the device. If an external tube of sufficient size to be clinically useful was simply attached at its distal end to the distal end of flexible endoscope, normal rotation of the endoscope would cause the external tube to become twisted (i.e., wrapped or spiraled) around the endoscope. A twisted external tube could not only impair the endoscope's ability to be further rotated and/or flexed, it could also compromise the passageway within the external tube by producing too tortuous of a path for instruments to freely pass and by narrowing the width of the passageway. If the external tube is rigidly fixed (e.g., taped or glued) at other points along the endoscope in addition to at its distal end, the tube could significantly compromise the endoscope's flexibility by making the endoscope much less flexible in the direction towards the fixed external tube or in the opposite direction away from the fixed tube. Further, an external tube attached only at one common distal or a few fixed points, could increase the risk that tissue structures could get stuck or pinched between the endoscope and the external tube during use by causing the endoscope and the external tube to flex away from each other and then back together.

The tube guides of Claim 2 each have an opening that permits the external tube to slide back and forth in the direction of this opening within the tube guide. By using multiple tube guides attached at the same circumferential location along an endoscope, the external tube passing through the openings in the tube guides will maintain its relative circumferential orientation along the length of the endoscope even during endoscope rotation. The external tube can rotate together with the endoscope within the attached tube guides to avoid having only part of the external tube (e.g., the distal end) moving while the remainder of the external tube twists around the rotating endoscope. By enabling the external tube to rotate along the length of the endoscope and with the endoscope, twisting and malformation of the external tube can be

avoided. By enabling the external tube to slide within the tube guide, the endoscope can be more readily flexed toward and away from the direction of the external tube because the external tube can slide away from or towards the tip along the inside or the outside of the curve, respectively. In other words, the sliding tube eliminates putting the external tube under compression during endoscope flexion towards or under tension when the endoscope flexes away from the tube. Further, by maintaining the external tube in the same relative position near the endoscope, the potential formation of a tissue catching gap or wide opening between the endoscope and external tube can be avoided.

Mere attachment of a clip (61) near the distal end of tube (2) in Ishikawa (see FIGS. 6A and 9A) does not solve the problems discussed above along the length of the endoscope. Moreover, the tube (2) is not described in Ishikawa as being slidable through its clip (61), see column 6, lines 27-45, and column 8, lines 20+. Thus, Claim 2 is patentable over Swain '153, Swain '730, Yoon, and Ishikawa, either alone, or in combination, and withdrawal of the rejection of Claim 2 is requested.

Claim 27 has been rewritten in independent form with all limitations of the Claim 1 prior to this Amendment. This claim describes a port on the flexible tube for enabling suction to be provided to the distal tissue engaging end of the suturing instrument via an opening in a channel of the tissue engaging end. No such port on a flexible tube and opening in a channel of a tissue engaging end for providing suction is present or even suggested in Swain '153, even in combination with Swain '730, Yoon, and Ishikawa. Thus, Claim 27 is patentable over Swain '153 , Swain '730, Yoon, Ishikawa, either alone or in combination, and withdrawal of the rejection of Claims 27 is requested.

Claim 29 describes means for locking the position of the at least one of the instruments of Claim 1 with respect to the flexible tube at the tip of the flexible tube. There is no flexible tube having a tip as provided for in Claim 29, since the combination of Swain '153, Swain '730, Yoon, and Ishikawa, fails to describe or suggest such locking means. Thus, Claim 29 is patentable over Swain '153 or '730, Yoon, Ishikawa, either alone or in combination, and withdrawal of the rejection of Claim 29 is requested.

With respect to Claim 30, there clearly are no protrusion members along the outer surface of the distal end of either devices of Swain '153 or '730, and no tip having an opening with one or more slots into which such protrusion members are receivable to lock the position of any instrument. Thus, Claim 30 is patentable over Swain '153, Swain '730, Yoon, and Ishikawa either alone or in combination, and withdrawal of the rejection of Claim 30 is requested.

Claims 31 and 32 describe means for steering the distal tissue engaging end of the suturing instrument of Claim 4. No such steering means is shown at the distal of the sewing device of Swain '153, even in combination with Swain '730, Yoon, and Ishikawa. Claim 32 further describes the steering means as being one of hydraulically and mechanically actuated. Thus, Claims 31 and 32 are patentable over Swain '153, Swain '730, and Yoon, and Ishikawa either alone or in combination, and withdrawal of the rejection of Claims 31 and 32 is requested.

Claim 44 describes a system for endoscopic suturing in the body of a patient having an endoscope with a shaft and an internal channel along the shaft locatable in the body of a patient, a suturing instrument having at least a partially flexible shaft which is locatable through the internal channel of the endoscope to locate at least one loop of suture in the body of a patient, and a suture securing instrument having at least a partially flexible shaft which is locatable through the internal channel of the endoscope to retain in a sleeve member the loop of suture and then cut the suture extending from the sleeve member to secure the suture in the body of the patient. First, the sewing device of Swain '153 and cutting device of '730 are mounted upon an endoscope, utilizes an endoscope's biopsy channel 3 of Swain '153 (column 1, lines 57-58, column 2, line 1) or biopsy channel 2 of Swain '730 (column 1, lines 32-33 and 51-54) to operate their respective devices, and both have a viewing channel conventional to endoscopes (see column 1, lines 52-54, of Swain '153, and column 1, lines 35-36, of Swain '730). Thus, there is no reason for passing the devices of Swain '153 or '730 through an internal channel of another endoscope, as their devices already incorporate features of a conventional endoscope, and the biopsy channel of such endoscope is presently in use. Yoon is not an endoscope, as it lacks the important feature of an endoscope, i.e., viewing. Second, the cutting device of Swain '730 fails to retain any suture through a sleeve member. Thus, the combination of Swain '153, Swain '730, and Yoon does not describe or suggest any endoscope having a channel through which the claimed suturing and suture securing instruments may pass through. Withdrawal of the rejection of Claim 44 is hence requested.

Claim 73 describes a system of endoscopic suturing having means for attaching an external tube along a flexible shaft of an endoscope to flex with flexing of the shaft, a suturing instrument locatable through the external tube attached to the endoscope to locate at least one loop of suture through tissue in a body of a patient, and a suture securing instrument having at least a partially flexible shaft which is locatable through the external tube attached to the endoscope to retain in a sleeve member the loop of suture and then cut the suture extending from the sleeve member to secure the suture in the tissue. No suture securing instrument is provided

in Swain '153 or 730, Yoon, or Ishikawa, which retains in a sleeve member the loop of suture and then cuts the suture extending from such sleeve member to secure the suture in the tissue. Therefore, Claim 73 is patentable over Swain '153, Swain '730, Yoon, and Ishikawa, either alone, or in combination, and withdrawal of the rejection of Claim 73 is respectfully requested.

Claim 74 describes a system of endoscopic suturing having an endoscope locatable in the body of a patient having a flexible shaft with a steerable distal end, a flexible guide tube having first and second ends locatable outside the shaft, and have the first end attached to the distal end of the shaft to be steered with steering of the distal end of the endoscope, and at least one tissue suturing instrument and one suture securing instrument. Each of these instruments has a shaft which is sufficiently flexible to be insertable through the flexible guide tube when the flexible guide tube is located in a body of a patient. For reasons argued with respect to Claim 1, Claim 74 is patentable over Swain '153, Swain '730, Yoon, and Ishikawa either alone, or in combination, and withdrawal of the rejection of Claim 74 is respectfully requested.

The Examiner found Claims 8-18 as being allowable if rewritten in independent form. Claim 8 has been rewritten with all the limitations of Claim 1, and thus should stand allowed. Claims 9-18 depend on Claim 8 and thus should also stand allowed.

Non-elected Claims 33-43 and 49-72 are cancelled without prejudice, as Applicants intend on filing one or more divisional applications contained such claims. Claim 4 is amended and Claim 21 is cancelled in light of the Amendment of their base Claim 1. Dependency of Claims 5, 7 and 22-24 have been revised.

Applicants enclose an article by a clinical investigator at the John Hopkins Bayview Medical Center. This article written by Dr. Michael Schweitzer entitled "Endoscopic Intraluminal Suture Plication of Gastric Pouch and Stoma in Postoperative Roux-en-Y Gastric Bypass Patients", Journal of Laparoendoscopic and Advance Surgical Techniques, Vol. 14, No. 4, 2004, describes the benefit of the claimed system, referred to as the Flexible Endoscopic Suture Device (ESD) in this article regarding treatment of gastroesophageal reflux disease (GERD). In describing the system, the article refers to the suturing instrument as the Sew-Right® device, the suture securing instrument as the Ti-Knot® device, and the flexible tube attached to the endoscope as the external accessory channel. This article makes evident the clinical success of the present invention for one important application of endoscopically placing sutures in the stomach to deal with GERD.

Applicants also enclose an article, entitled, "The Many Paths to Design Excellence," from a medical industry publication, MX: Business Strategies for Medical Technology Executives,

pp. 46-53, May/June 2002, which highlights the invention and its company on page 48 under the subtitle of "A Winning Culture." The present invention was selected as a winner of a 2002 Medical Design Excellence Award in the category of "Surgical Equipment, Instruments and Supplies."

Claims 75-82 have been added to the Application. Claim 75 depends on Claim 74 and describes the tube guides, which for reasons argued earlier are patentable over Swain '153, Swain '730, Yoon, and Ishikawa. Claim 76 describes the tube guides of claim 2 as being attachable at the same circumferential position along the shaft. Claim 77 describes that at least one of the instruments of Claim 2 is a suturing instrument or a suture securing instrument. Swain '153, Swain '730, Yoon, and Ishikawa do not describe or suggest the tube guides or such instruments passing through the flexible tube of Claims 76 and 77. Claims 78-81 depend on Claim 2, and are similar to Claims 30, 26, 27, and 31, respectively, which for reasons described earlier, are patentable. Claim 82 has language similar to allowable Claim 8.

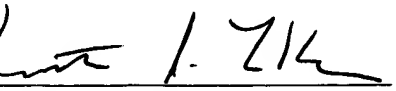
Claims 83-89 have also been added to the Application. Claim 83 describes a system having a flexible tube, a member for distally attaching the endoscopes shaft and a flexible tube in which the flexible tube provides a conduit for passage of one or more instruments along side the shaft, and one or more tube guides attachable along substantial length of the shaft. Each of the tube guides has an opening through which the flexible tube extends, and the flexible tube slides through the openings of the tube guides when the endoscope's shaft is flexed over multiple dimensions to maintain said flexible tube in a substantially coaxial orientation with the shaft.

Ishikawa does not describe or suggest any tube guides attached along side an endoscope's shaft such that when such shaft is flexed over multiple dimensions the flexible tube is maintained in a substantially coaxial orientation with that shaft. Claims 84-89 depend on Claim 83, and are similar to Claims 76-81 described above. Thus, Claims 83-89 are patentable over Swain '153, Swain '730, Yoon, and Ishikawa, either alone or in combination.

A petition for a three month extension of time and a Request for Continued Examination enclosed with this Amendment, along with a check for the petition fee.

Respectfully submitted,

Dated: 11/24/04



Kenneth J. LuKacher
Attorney for Applicant(s)
Registration No. 38,539

South Winton Court
3136 Winton Road South, Suite 204
Rochester, New York 14623
Telephone: (585) 424-2670
Facsimile: (585) 424-6196

Enclosures: Combined Amendment and Petition for Extension of Time Transmittal Letter and Check in the amount of 490.00;
Two References;
3 Certificates of Express Mailing, Express Mail No. EV 325177174 US;
Request for Continued Examination and check in the amount of $395.00; and
Listing of Claims.

The Many Paths to Design Excellence

The winners of this year's Medical Design Excellence Awards are united by a common focus on effective medical design.

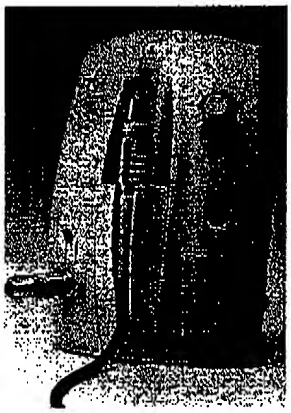
Renee DiIulio

When John Bottjer purchased Geiger Instrument Co. in 1995, he knew that its long-term future was uncertain. The company had manufactured thermal cautery units for more than 80 years, and change had been slow in coming. The company's then-current cautery unit had not been updated in more than four decades. A redesign "was a matter of survival for Geiger," Bottjer recalls. "The previous unit had stable sales with little growth potential and was insufficient for the company to continue long term."

As part of the turnaround, the company was renamed Geiger Medical Technologies and relocated to Monarch Beach, CA. More importantly, though, Bottjer set out to update the company's flagship thermal cautery unit. He began with an intense period of analyzing the market and interviewing users. Then, together with an electronics expert from Houston and a student from the Art Center College of Design in Pasadena, CA, Bottjer redesigned the product.

John Bottjer

Funded from cash flow, consulting projects, and partnerships (the electronics expert and design student agreed to accept royalties in lieu of an upfront fee), the reborn Thermal Cautery Unit Model 150 featured a modern look and an affordable price. Moreover, it was now suitable for overseas sales, whereas the previous unit was not even 220-V adaptable. Sales of the redesigned unit have increased by 600%, and have already covered the cost of development.



The Thermal Cautery Unit Model 150, by Geiger Medical Technologies (Monarch Beach, CA).

Bottjer's achievement is a testament to the power of effective medical design. Good design can energize a stagnant company or create the foundation of a new one, increase market share or create entirely new markets, and give a rapid start to a new product or repay agonizingly long development and regulatory approval times. Above all, it can improve patients' lives.

The 2002 Medical Design Excellence Awards (MDEA) celebrate the ways in which medical device companies have leveraged good design into corporate success. As the sampling of winning companies profiled here suggests, companies took many different paths to their achievements. All of them, however, share a commitment to design excellence.

Innovating Tradition

Another company to win an MDEA this year for redesigning a longtime flagship product is Welch Allyn Inc. (Skaneateles Falls, NY). Though a large and well-established company, Welch Allyn nonetheless emphasizes innovation. As laid out in its mission statement, the company's strategy is to "strengthen its position in a variety of fields worldwide by continually enhancing and leveraging its core technologies." In 2001, Welch Allyn launched seven

new or redesigned products. Three won MDEAs this year, an unprecedented achievement.

One of these, the PanOptic Ophthalmoscope, is a reintroduction of the product on which the company was founded in 1915, and which has been a key contributor to its financial success. During a "Big Bang" discussion, a company team decided that it would make a "big bang" if Welch Allyn could significantly expand the ophthalmoscope's field of view and therefore strengthen its lead in this technology. With specific goals, including retrofitting the product to the same base of handles currently available, the team succeeded in expanding the field of view from 5° to 25°. Marketed to hospitals and physician offices through both distributors and the Welch Allyn sales force, the product has sold better than anticipated, generating a high rate of adoption among medical students.

Company president and CEO Peter Soderberg claims two secrets to his company's design success: team effort and attention to customer needs. "We generally have tight unit-cost and customer-satisfaction goals when developing a product," says Soderberg. Fairy dust doesn't hurt either; teams are able to spend money without formal approval in the early stages. The MDEAs, says Soderberg, provide recognition for successful design. But more importantly, he adds, the awards offer positive testimony about the people and the environment at Welch Allyn.

Peter Soderberg

As in the case of Welch Allyn, the design achievements of the Medical Carbon Research Institute LLC (MCRI; Austin, TX) grew out of a combination of tradition and innovation. In 2002, MCRI won an MDEA for the On-X Valve, a mechanical heart-valve prosthesis. The On-X valve mimics the function of the natural human valve so closely that hemodynamic clinical results are nearly equivalent.

The PanOptic Ophthalmoscope by Welch Allyn Inc. (Skaneateles Falls, NY).

"The company, founded in 1994, may seem new, but the core of MCRI is actually 30 years old," says MCRI team member Jon Stupka. In the 1960s, MCRI president Jack Bokros, PhD, developed pyrolytic carbon with heart surgeon Michael DeBakey for use in replacement heart valves. Bokros has since made carbon parts for more than 90% of all mechanical heart valves produced, founding a series of companies along the way.

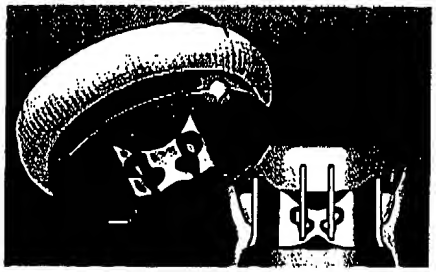
In a continuation of this tradition, he and his MCRI associates patented the first 100%-pure medical pyrolytic carbon, On-X carbon, a key component of the winning On-X valve. Describing it as the first major advance in biomedical carbon materials technology since Pyrolite carbon, Bokros says it is stronger, tougher, and more easily incorporated into a wide variety of devices than any previous pyrolytic carbon.

Jack Bokros

Start-Ups: Kick-Starting New Traditions

If innovative design is beneficial to established companies, it is crucial to start-ups. For two such companies, winning an MDEA this year reflects the credibility and exposure that can come from well-designed products, and on which growth is based.

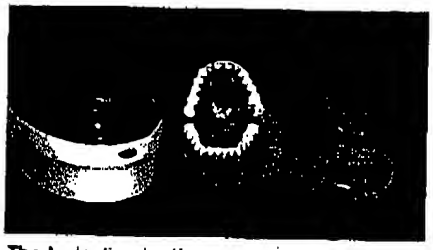
Align Technology Inc. (Santa Clara, CA) is just now seeing word of mouth help spread the news about its MDEA-winning product, Invisalign. A method of straightening teeth, Invisalign involves two components, ClinChek and Aligners. ClinChek is an Internet-based system for three-dimensional clinical modeling of a course of treatment. The resulting data are used to make a series of clear, removable Aligners to be worn for two weeks, each one corresponding to a stage of tooth movement.



The On-X Valve by the Medical Carbon Research Institute (Austin, TX).

The product was conceived by company cofounder and chairman of the board Zia Chishti. After having gone through the embarrassment of wearing braces as an adult, Chishti noted that the retainer he subsequently wore could also move his teeth, but only within a limited range. With a background in computer science, he realized that a series of devices similar to his retainer could be designed with rapid prototyping technology to create a replacement for braces.

With Kelsey Wirth, now company president, he founded Align Technology. The two developed the business plan while students in the MBA program at Stanford University and secured funding from local venture capitalist groups.



The Invisalign teeth-straightening system by Align Technology (Santa Clara, CA).

The company had to surmount challenges related to training practitioners and a requirement for in-office Internet access, but thereafter the product was readily accepted. The company markets Invisalign primarily itself, supplementing its efforts with one distributor in Israel and one in North America to target general practitioners. According to Amir Abolfathi, vice president of research and development, the concrete recognition provided by the MDEA will lend further credibility to the product's design.

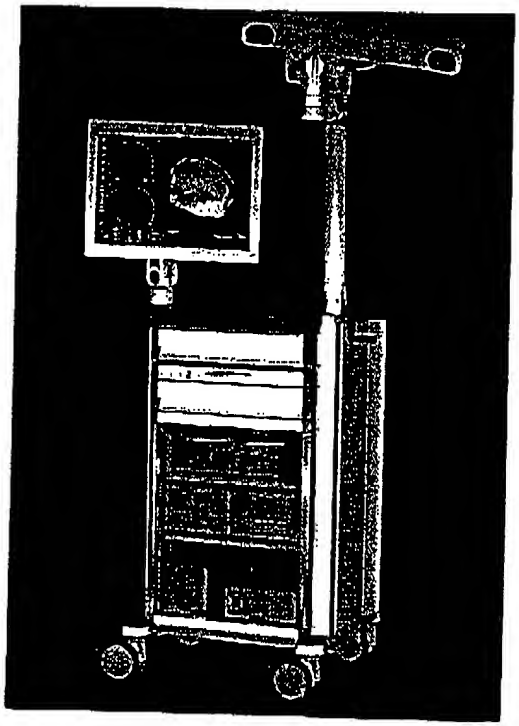
Amir Abolfathi

Another first product to win an MDEA this year was the Cbyon Suite, from Cbyon Inc. (Mountain View, CA). It provides neurosurgeons, ENT surgeons, and spine surgeons an image-guided surgery product that can visualize internal anatomical structures beyond the direct field of view. This is achieved through conversion of 2-D radiological images into a 3-D model of the patient's anatomy. According to S. Mitchell Seyedin, PhD, Cbyon's CEO, president, and cofounder, the product is intimately tied to the corporate mission: "to provide clinically relevant, cost-effective equipment to empower surgeons to apply minimally invasive techniques that are otherwise difficult or impossible to treat."

S. Mitchell Seyedin

Funded by venture capital firms, Cbyon turned to the market to develop a successful product. "We relied on our clinical collaborators to tell us what they needed image guidance equipment to do to support their minimally invasive surgeries. One element of the feedback revolved around product cost and the necessity to create a device that was cost-effective, intuitive, and easy to upgrade," says Seyedin. Cbyon uses different hardware and software to achieve this aim. Now the company will focus on exposure.

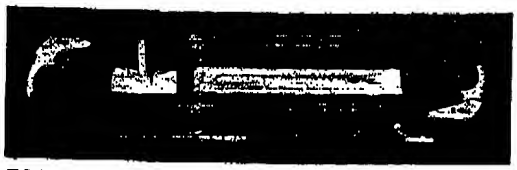
"Winning the MDEA validates our product and efforts. Being a newcomer to the image-guided



The Cbyon Suite from Cbyon Inc. (Mountain View, CA).

A Winning Culture

Winning an MDEA in one year validates the success of a project. But having won the award three years in a row, as LSI Solutions (Victor, NY) has done, says president and CEO Jude S. Sauer, MD, underscores the company's culture of innovation. Winner of a 2002 MDEA, the ESD Flexible Endoscopic Suturing Kit is used during endoscopic therapeutic interventions. The kit provides a safe and effective means to utilize long, narrow, flexible instruments to ergonomically suture gastrointestinal tissue sites that lie within approximately 70-cm of the mouth or anus.



ESD Flexible Endoscope by LSI Solutions (Victor, NY).

LSI supplies the ESD kit exclusively to Wilson-Cook Medical Inc. (Winston-Salem, NC), which supports further development, marketing, and sales. LSI selected Wilson-Cook after reviewing a number of potential partners. Wilson-Cook's expertise in flexible endoscopy as well as its international presence were influencing factors in the decision. The arrangement allows LSI to continue focusing on its core competency in minimally invasive surgery.

surgery arena, recognition by our peers and industry builds confidence among our existing customers and provides an opportunity to tout our accomplishments to potential customers," says Seyedin.

Long and Short Views

For many companies, not only recognition, but a marketable product, is a long time coming. In development since 1992, the Duplex Drug Delivery System made by B. Braun Medical Inc. (Bethlehem, PA) finally reached the market in 2001. The Duplex system is a ready-to-use, multichambered bag that stores a drug, or drugs, and diluent in separate compartments until the IV is ready to be administered.

After conducting extensive market research utilizing more than 250 clinicians, a B. Braun team determined the parameters for a drug-delivery system that addressed the process by which drugs are mixed and administered. Ron Earle, group senior vice president at B. Braun, notes that B. Braun has made this product one of its largest single investments in technology. "We are now ready to sell the product and expand its use," says Earle. "We've placed the product in a separate business unit to exploit the technology as much as possible. Winning the MDEA lends credence to our investment while increasing awareness of the product."

The Duplex Drug Delivery System by B. Braun Medical Inc. (Bethlehem, PA).

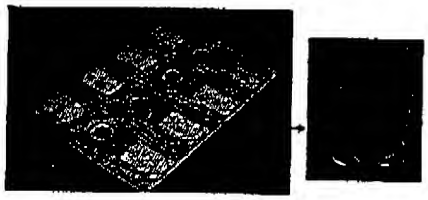
Another 2002 MDEA-winning product with a long development time is Dermagraft, made by La Jolla, CA–based Advanced Tissue Sciences Inc. (ATS). A cryopreserved, tissue-engineered, allogeneic, human dermal replacement, Dermagraft provides healthy, metabolically active tissue to enhance wound closure.

In contrast to B. Braun, ATS cannot yet finance its own research. Instead, it relies on Wall Street and investment groups for ongoing funding, says Dawn Applegate, PhD, director of technology development at ATS. The publicity resulting from the MDEA, she observes, helps provide positive exposure to these groups.

ATS funded Dermagraft primarily through a joint venture with Smith & Nephew (London), a European leader in wound care. The two partners split costs and profits evenly, says Applegate.

Dawn Applegate

Because it can take years to get such a product approved, ATS chose its market carefully. Diabetic foot ulcers, for which the product has FDA approval, are considered life threatening. Such conditions are granted an accelerated approval process. Regardless, says Applegate, the product took 10 years to get to market.



Dermagraft by Advanced Tissue Sciences (La Jolla, CA).

Because Dermagraft is the first living-tissue engineered product to be marketed, it has met with some challenges, including the training of physicians in its handling and use. Yet the company has approached these problems as innovatively as the product itself. It anticipates significant sales this year, particularly because diabetic foot ulcers represent a larger market than the first approved application, which was for burn treatment.

"Tissue engineering has not yet had a blockbuster product

Innovating for the Market

Innovation is not a required element of good design, but some companies insist on it regardless. One example is MDEA winner Coloplast (Marietta, GA), which, according to its mission statement, "strives to offer preferred product ranges based on innovation, advanced technology, and cost-effectiveness." Coloplast has been a leader in Europe since inventing the first disposable ostomy pouch in 1957. It has been gaining market share in the United States for the past 15 years by means of its innovative technology. Its winning MDEA entry, the Assura EasiClose, a drainable ostomy pouch with an integrated hook-and-loop closure system, currently has no competitors.

Assura EasiClose colostomy system by Coloplast (Marietta, GA).

Coloplast developed the product with clinician input and focus-group feedback. The resulting strong demand is expected to contribute positively to the Assura division's sales. Says Brad Selman, marketing director, "Being a recipient of the MDEA lends credibility to our claim as innovators in the field."

2002 MDEA Winners

The 28 winning products in the 2002 Medical Design Excellence Awards (MDEA) competition were selected from scores of entries by a panel of nine expert jurors. Presentation of the gold and silver awards will take place on Wednesday, June 5, at the Medical Design & Manufacturing East 2002 Conference and Exposition, in New York City.

Critical-Care and Emergency Products
- SpeedBlocks Head Immobilizer, manufactured by Laerdal Medical Corp. (Wappingers Falls, NY).

Dental Instruments, Equipment, and Supplies
- 3M ESPE Elipar FreeLight Cordless LED Curing Light, manufactured by 3M ESPE AG (Seefeld, Germany).
- HealOzone TEC3, manufactured by Micro Motors (Santa Ana, CA).
- Invisalign teeth-straightening system, manufactured by Align Technology Inc. (Santa Clara, CA).

Finished Packaging
- Duplex Drug Delivery System, manufactured by B. Braun Medical Inc. (Irvine, CA).
- Kryotrans transport system, manufactured by Kryotrans Ltd. (London, UK).

General Hospital Devices and Therapeutic Products
- GSI Audioscreener, manufactured by GSI Viasys Healthcare (Madison, WI).
- Nellcor OxiFirst Fetal Pulse Oximetry System, manufactured by Nellcor (Pleasanton, CA).
- TherOx AO System, manufactured by TherOx Inc. (Irvine, CA).
- Welch Allyn Ear Wash System, manufactured by Welch Allyn Inc. (Skaneatekes Falls, NY).

Implant and Tissue-Replacement Products
- Ancure Endograft System, manufactured by Guidant Corp. (Menlo Park, CA).
- Dermagraft, manufactured by Advanced Tissue Sciences (La Jolla, CA).
- On-X Valve, manufactured by the Medical Carbon Research Institute (Austin, TX).
- Strata CSF shunt, manufactured by Medtronic Neurosurgery (Goleta, CA).

In Vitro Diagnostics
- Accu-Chek Compact, manufactured by Roche Diagnostics Corp. (Mannheim, Germany).

Over-the-Counter and Self-Care Products
- Welch Allyn DuraShock Integrated Aneroid Sphygmomanometer, manufactured by Welch Allyn Inc. (Skaneateles Falls, NY).
- SimpleJect Auto-Injector System, manufactured by Owen Mumford Ltd. (Oxford, UK).
- SleepStrip Disposable Sleep Apnea Screener, manufactured by SLP Ltd. (Tel Aviv, Israel).

Radiological and Electromechanical Devices
- DigitEyes laser slit lamp, manufactured by Bausch & Lomb (Salt Lake City, UT).
- Given Diagnostic Imaging System featuring the M2A Capsule, manufactured by Given Imaging Ltd. (Yoqneam, Israel).
- OptiGo, manufactured by Philips Medical Systems (Andover, MA).
- PanOptic Ophthalmoscope, manufactured by Welch Allyn Inc. (Skaneateles Falls, NY).

Rehabilitation and Assistive-Technology Products
- Assura EasiClose drainable ostomy pouch, manufactured by Coloplast (Marietta, GA).

Surgical Equipment, Instruments, and Supplies
- Cbyon Suite, manufactured by Cbyon Inc. (Palo Alto, CA).
- ESD Flexible Endoscopic Suturing Device, manufactured by LSI Solutions (Victor, NY).
- StealthStation Treon Treatment Guidance System, manufactured by Medtronic SNT (Louisville, CO).
- Thermal Cautery Unit Model 150, manufactured by Geiger Medical Technologies Inc. (Monarch Beach, CA).
- UltraCision Harmonic Scalpel Generator 300, manufactured by Ethicon Endo-Surgery (Cincinnati, OH).

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Endoscopic Intraluminal Suture Plication of the Gastric Pouch and Stoma in Postoperative Roux-en-Y Gastric Bypass Patients

MICHAEL SCHWEITZER, MD, FACS

ABSTRACT

Background: **Endoscopic intraluminal suturing is currently used to treat gastroesophageal reflux disease. This new field of intraluminal gastric surgery may benefit postoperative Roux-en-Y gastric bypass patients. While gastric bypass is highly successful in the majority of patients, significant weight regain can occur over time due to stretching of the gastric pouch and stoma.**

Methods: **Between November 2002 and January 2003, four patients who previously underwent gastric bypass (GBP) surgery presented with dilated gastrojejunostomy (GJ) anastomosis and weight regain. They gave their consent and were taken to the operating room for upper endoscopy, where they were placed under general anesthesia. Using a flexible endoscopic suturing device with a standard 11-mm endoscope, the dilated GJ anastomosis was plicated to reduce its size, and in two of the patients the gastric pouch was also plicated.**

Results: **Successful stomal plication was performed on all four patients to narrow their dilated stomas that measured > 2 cm preoperatively to < 15 mm postoperatively. Patients were told to go on a puree diet for 4 weeks. One patient had a repeat procedure due to rupture of one suture after eating solid food two weeks after the surgery. The stoma was then plicated with 3 sutures. Two patients had their gastric pouch plicated near the stoma. All patients to date report feeling full earlier with decrease caloric consumption and subsequent weight loss.**

Conclusion: **Upper endoscopic intraluminal suturing represents a new field of emerging technology that will certainly find its role in the postoperative bariatric patient. Both the gastric pouch and stoma are within reach for endoscopic intraluminal therapy. How it can aid our patients is currently being studied.**

INTRODUCTION

ENDOSCOPIC INTRALUMINAL SUTURING technology is a new field of minimally invasive surgery that holds promise for treating upper gastrointestinal disorders. Three companies are taking the lead in the development and refinement of endoscopic devices that can be used to place and then tie sutures. The EndoCinch® (Bard, Billerica, Massachusetts) is approved by the Food and Drug Administration (FDA) for the treatment of gastroesophageal reflux disease (GERD). It was developed by Dr. Paul Swain, who invented the endoscopic sewing machine. The device involves placing suture through gastric tissue that is suctioned into a chamber and then endoscopically pushing a needle through the tissue. The two suture strands of the plication are then tied with 4 to 6 half-hitch knots. Wilson-Cook (Winston-Salem, North Carolina) currently has an FDA-approved Flexible En-

The Johns Hopkins University School of Medicine, Baltimore, Maryland.

doscopic Suture Device (ESD)® for GERD. It uses an external accessory channel taped to an endoscope which delivers a longer version of the Sew-Right® device to suture plicate gastric tissue under suction. The Ti-Knot® device is then used to place a titanium knot. NDO Surgical (Mansfield, Massachusetts) is in the process of obtaining FDA approval for its Full Thickness Plicator™. Instead of suction it uses a tissue retractor to pull the tissue into the suture device that when fired delivers a pretied pledgeted suture to plicate the gastric tissue.

Roux-en-Y gastric bypass is a highly successful weight loss operation that has been shown in many clinical studies to obtain 67–75% excess weight loss within 2 years for more than 80% of the patients.[1,2] A fourteen year followup study has shown a 50% excess weight loss maintained by 95% of patients.[3] Weight regain over time has been attributed to several factors: changes in diet, such as nibbling high calorie carbohydrates such as potato chips; the gastrojejunostomy (GJ) anastomosis may dilate and lead to faster emptying that will not leave patients satisfied with their meals; or the gastric pouch may also dilate, and thereby hold more food with less satiety produced from smaller meals.[4] Attempts to reduce the size of the gastric pouch and stoma diameter by revisional surgery have led to controversial results.[5] Patients who regain significant weight after gastric bypass surgery may be more likely to dilate their gastric pouch and stoma after a revision. Revisional surgery also has a higher leak rate due to scar tissue and changes in the vascular supply. Endoscopic intraluminal suturing of the dilated stoma and pouch is currently the least invasive revisional surgical technique that may lead to sustained weight loss or just stop the upward progression of weight regain.

METHODS

From November 2002 to January 2003, four patients who previously underwent Roux-en-Y gastric bypass with a divided gastric pouch were considered for intervention to stop weight regain and possibly induce weight loss. Two of the patients had originally been treated by another bariatric team at a different facility. All four patients underwent upper gastrointestal barium radiological exam and/or upper endoscopy to evaluate the gastric pouch and stoma diameter. They all had dilated stoma diameters at the GJ anastomosis and the two patients from an outside facility also showed an enlarged gastric pouch. The patients were counseled on better eating habits in hopes of improving outcomes. After informed consent, the patients were taken to the operating room, where general anesthesia was performed. The patients were then placed in the left lateral decubitus position. The Wilson-Cook ESD was used in all cases to plicate the stoma and in two cases to also plicate the gastric pouch. A standard single channel upper endoscope was used for the procedure. The external accessory channel that the sewing and knot device accesses is taped to the endoscope (Fig. 1). The Sew-Right device is lubricated and the prolene suture is loaded onto the two ferules. The Ti-Knot device is loaded with a titanium knot that is seated in place. The endoscope with accessory channel is then placed transorally into the gastric pouch. The Sew-Right is then loaded into the channel and the appropriate position on the stoma is chosen. Vacuum suction is applied to the Sew-Right, which pulls the tissue into its chamber (Fig. 2). The needle with suture is applied through the tissue by squeezing the handle, after which the vacuum is turned off. The lever is then switched to the other needle (left or right) and again the site is chosen to apply the second needle with suture. The Sew-Right is withdrawn and 4 suture tails are initially seen that really represent one continuous loop of suture; by withdrawing the device it becomes 2 suture tails with the stoma plicated between the left and right sutured sites. The Tie-Knot is loaded through the 2 sutured ends into a lubricated accessory channel. It is advanced down to the sutured tissue overtop the sutures, and squeezing the lever releases the titanium knot (Fig. 3). The sutures are cut by pulling on them. The titanium knot is visually checked (Fig. 4). The procedure is repeated as needed to reduce the size of the stoma or to plicate the gastric pouch near the stoma.

RESULTS

All four patients had successful stoma plication that reduced the size of the opening and also made it less compliant (Figs. 5, 6). Two of the patients had their gastric pouch plicated near the stoma. Surgery was performed on an outpatient basis in all cases, with no intraoperative complications. One of the four patients had a more difficult stoma plication due to the fact that the anastomosis was made on the greater curve side of a larger gastric pouch (the patient had her original operation done at an outside facility). She then overate on Thanksgiving and ruptured the suture. No intervention other than a proton pump inhibitor was instituted. The patient reported feeling less full and requested a repeat operation. Due to the difficulty of doing the greater curve anastomosis the first time, she was placed in the right lateral decubitus position the second time, which allowed us to place 3 sutures at the GJ anastomosis and also a gastric pouch plication near the stoma. All four patients were placed on puree diets for one month. All four report feeling full more quickly with subsequent weight loss being reported early on. No longterm data is available at this time.

Current technology now allows us to endoscopically place sutures inside the stomach. While the initial procedures have focused on GERD, certainly there are more

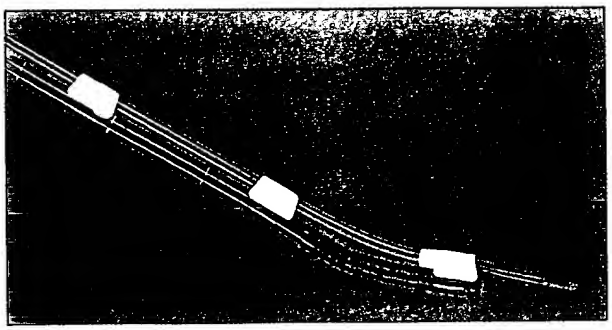

FIG. 1. The accessory channel attached to the endoscope.

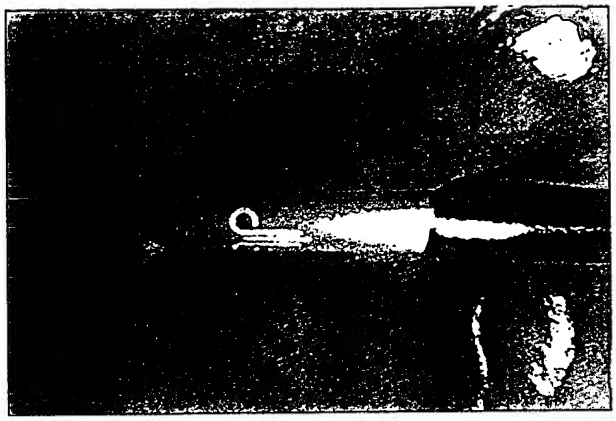

FIG. 2. The tissue is vacuumed into the Sew-Right Device® before the needle with suture is forced through it.

FIG. 3. The Tie-Knot Device® is passed over the two ends of suture before firing.

FIG. 4. The titanium knot is visually inspected.

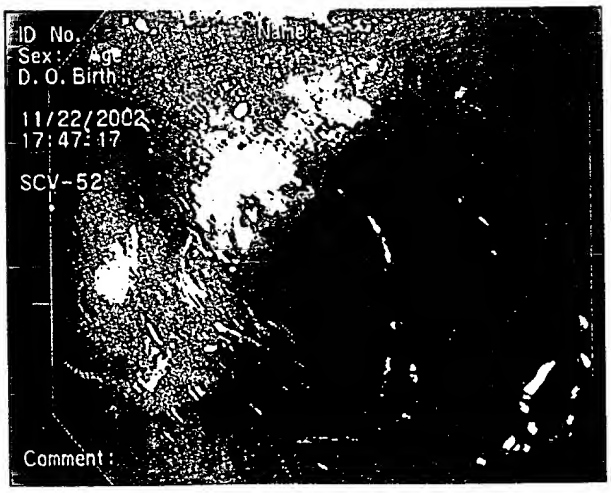

FIG. 5. The gastrojejunostomy anastomosis is shown. It is dilated to over 2 cm in size. The afferent and efferent sides of the Roux limb are seen through the dilated stoma.

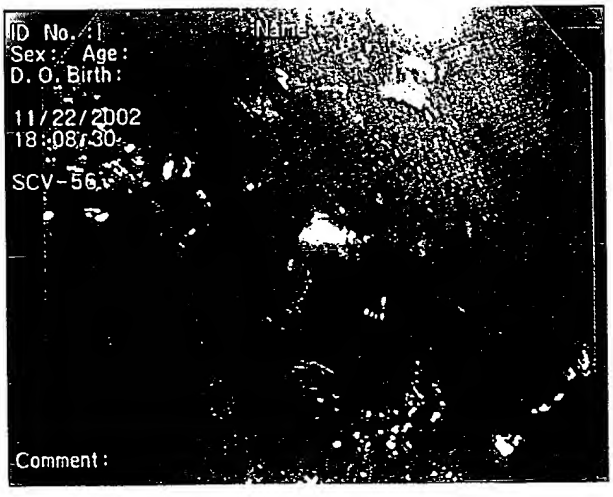

FIG. 6. The plicated stoma with titanium knot holds the prolene suture ends. The stoma is now under 15 mm in size.

possibilities now that we have access to the upper digestive tract with a suturing device.[6,7] Flexibility of the instrument may limit the areas of the stomach available to endoscopic suturing, but corporate research is focused on improving this.

The GJ anastomosis is usually constructed over a 30–32 French dilator or with a 21-mm circular stapler to produce a stoma approximately 10–12 mm in size.[8] Retrospectively, patients who regain a lot of weight commonly have a stoma that has dilated to over 2 cm. Patients who regain significant weight report feeling hungry all day with loss of satiety after meals. They also appear to adjust their diet to foods that go through the pouch easier.[9]

Open revision of a dilated stoma and/or gastric pouch is not always successful, especially since the patient may overeat and dilate it once again, thereby defeating the revisional operation.[2] The endoscopic suturing method allows us to reduce stoma size, and then be able to go back easily without the morbidity and mortality of higher risk repeat operation. This may be more beneficial since the stoma reduction can be easily repeated, stopping the dilating process while educating the patient on how to use their gastric pouch correctly. This is similar to the strategy used with adjustable gastric-banded patients whose balloons are filled with saline to tighten the stoma as they become less satiated with their meals. The goal is then for the patients to learn to use the gastric pouch correctly and to stop eating when they become full.

COMPETING INTERESTS

The author was a paid speaker for Wilson-Cook in May 2003.

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Address reprint requests to:
Michael Schweitzer, M.D.
Johns Hopkins Bayview Medical Center
Department of Surgery
4940 Eastern Avenue
Baltimore, MD 21224

E-mail: mschwei7@jhmi.edu